

**FAMOTIDINE - famotidine tablet, film coated**  
**HARRIS TEETER, LLC**

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***Drug Facts***

***Active ingredient (in each tablet)***

Famotidine USP 10 mg

***Purpose***

Acid reducer

***Uses***

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

***Warnings***

**Allergy alert:** Do not use if you are allergic to famotidine or other acid reducers

**Do not use**

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

**Ask a doctor before use if you have**

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating, or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

## **Ask a doctor or pharmacist before use if you are**

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

## **Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days

## **If pregnant or breast-feeding,**

ask a health professional before use.

## **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

## ***Directions***

- adults and children 12 years and over:
  - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
  - to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
  - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

## ***Other information***

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)
- protect from moisture

## ***Inactive ingredients***

carnauba wax, corn starch, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, sodium starch glycolate, talc and titanium dioxide.

## ***Questions or comments?***

call **1-855-274-4122**

## Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**JUST ONE TABLET** prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

**PROUDLY DISTRIBUTED BY:  
HARRIS TEETER, LLC  
MATTHEWS, NC 28105**

Made in India

Code: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (30 Tablets Container Label)**

**Harris Teeter™**

**ORIGINAL STRENGTH  
FAMOTIDINE TABLETS USP 10 mg  
ACID REDUCER**

Just One Tablet!  
Prevents & Relieves Heartburn  
Due to Acid Indigestion

**30**  
Tablets

**Do not use if printed foil seal on bottle is broken or missing.**

**Active ingredient (in each tablet)**  
Famotidine USP 10 mg. Acid reducer.

**Purpose**  
relieves heartburn associated with acid indigestion and sour stomach. prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages.

**Warnings** Allergy alert: Do not use if you are allergic to famotidine or other acid reducers. Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. with other acid reducers. Ask a doctor before use if you have heartburn over 3 months. This may be a sign of a more serious condition.

**Other information** chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders; or lightheadedness. frequent chest pain. frequent wheezing, particularly with heartburn. unexplained weight loss. nausea or vomiting. stomach pain. kidney disease. Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs. Stop use and ask a doctor if your heartburn continues or worsens.

**Directions** you need to take this product for more than 14 days. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222), right away.

**Other information** adults and children 12 years and over. to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. to prevent symptoms, swallow 1 tablet with a glass of water at any time from 15 to 60 minutes before eating food or drinking beverages that cause heartburn. do not use more than 2 tablets in 24 hours. children under 12 years: ask a doctor. Other information read the directions and warnings before use. keep the carton. It contains important information. store at 20° to 25°C (68° to 77°F). protect from moisture.

**Inactive ingredients** See carton for complete list of inactive ingredients.

**Questions or comments?** call 1-855-274-4122

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Made in India  
yourpharmacistguarantee.com

LM-4850 P14.308.11

Lot: 00000000X  
EXP: 04/2017  
Variables of Lot, EXP shall be printed online during packing.

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (30 Tablets Container  
Carton Label)**

**Harris Teeter™**

**ORIGINAL STRENGTH  
FAMOTIDINE TABLETS USP 10 mg  
ACID REDUCER**

**Just One Tablet!  
Prevents & Relieves Heartburn  
Due to Acid Indigestion**

CC  
Actual Size

**\*Compare to the Active Ingredient of  
Original Strength Pepcid® AC**

**30  
TABLETS**



# FAMOTIDINE

famotidine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69256-002
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)		FAMOTIDINE	10 mg	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)				
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
Color	PINK	Score	no score	
Shape	ROUND (biconvex)	Size	5mm	
Flavor		Imprint Code	CC;58	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-002-47	1 in 1 CARTON	08/03/2022	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA206531	08/03/2022		

**Labeler** - HARRIS TEETER, LLC (048463103)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(69256-002) , MANUFACTURE(69256-002)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(69256-002) , MANUFACTURE(69256-002)

Revised: 9/2022

HARRIS TEETER, LLC